

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 6/17/11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 25-31, 34-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Conte et al (USPN 6,294,200 hereafter '200) in view of Hayashida et al (USPN 5,593,694 hereafter '694).

The '200 patent teaches a coated tablet comprising a core and a coating (abstract). The core comprises layers (Figures), comprises an active pharmaceutical component comprising excipients (col. 4, lin. 55-65; col. 7, lin. 53-col. 8, lin. 26) and a swelling components (col. 5, lin. 29-40). The swellable components comprise swellable components like cellulose wicking agents, osmogents like lactose, (col. 5, lin. 10-25). The formulation comprises a second active ingredient that is release in an immediate release form (part 5, col. 3, lin. 60-65). The coating

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surrounds the core layers with the swellable layer in contact with the coating (part 2, Figure 3).

The swellable components are present as an in-lay tablet layer surrounding by the coating

(Figures). Upon release, the immediate release portion is removed and exposes the core layers.

The coating polymer is impermeable to the drug composition comprising cellulose phthalates

(col. 6, lin. 25-45). The removed immediate release coating acts a passageway on the coating for

the active agent to be released. The formulation is further coated with pH dependent coating

(col. 7, lin. 10-20).

The '200 patent discloses an orally administerable drug delivery system comprising a core and a coating. The coating surrounds the core, where the core comprises active agent regions. The coating has a region is operable to be removed while the remaining coating does not dissolve. The reference is silent to the inclusion of semipermeable coatings. However, the inclusion of semipermeable coating is well known the art as seen in the '694 patent. The semipermeable coating is a blend of permeable and impermeable coating compounds that allow for water to permeate without disintegrating completely. These types of polymers are found in the '694 patent.

The '694 patent teaches an oral administrable drug delivery system comprising a core and a coating (abstract). The core comprises an active ingredient along with an excipient (col. 5, lin. 60-col. 6, lin. 65). The core tablet further comprises swellable portions (col. 4, lin. 34-60). The core is surrounded by a coating that is in immediate vicinity of the drug and swellable portions. The periphery of the coated tablet is thinner than the top and bottom and upon administration will absorb water (col. 4, lin. 12-34). The coating is semipermeable to water around the edges (col. 7, lin. 10-20). The water absorption activates the water swellable portions of the core tablet

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forcing release of the active agent, while the top and bottom portions of the coating remain intact (Figures 2A, 2B). The sides of the coating are preselected to be removed after contact with the aqueous environment of the body, while the top and bottom portions are not removed (*Ibid.*) Since the tops and bottom of the dosage form does not dissolve or transmit drug to the aqueous environment, the side act as passageways for the drug to move through. The swellable agents include cellulose wicking agents, and osmogents such as lactose (col. 5, lin. 60-65). The dosage form is capable of zero-order release of the active agents (col. 7, lin. 30-35). The solid core tablet is a compressed tablet comprising a single layer of the components comprising both the active ingredient components and the swellable composition (Examples). It would have been obvious to include the semipermeable polymer combination to the coating of the '200 formulation in order to provide a more precise release of the drug core.

With these aspects in mind one of ordinary skill in the art would have been motivated to combine the semipermeable coating components of the '694 patent into the surrounding coating of the '200 patent in order to provide a more precise drug release. The artisan would have been motivated since the semipermeable coating of the '694 patent comprises similar cellulose polymers found in the '200 patent. The combination of the '200 and 694 patent would provide an orally administrable coating where the coating and a core. By combining the semipermeable polymer combination of the '694 patent into the tablet coating of the '200 patent the core would be surrounded by a water soluble polymer. It would have been obvious to combine the prior art with an expected result of stable coated tablet with a precision release rate, with more control.

Response to Arguments

Applicant's arguments filed 6/17/11 have been fully considered but they are not persuasive. Applicant argues that the instant claims are not obvious over the combination of prior art since the combination of prior art combination does not provide for a tablet having a single coating layer surrounding a core having two separate regions: an active ingredient layer and a swellable or reactive layer as currently claimed.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Regarding Applicant's argument it remains the position of the Examiner that the prior art continue to obviate the instant claims. The '200 patent provides the core with separate regions comprising an active region (part 1) and a swellable/reactive region (part 2). The core comprises multiple regions and is covered on three sides with a water insoluble polymer coating. The '200 patent differs from the instant claims in that the water insoluble coating does not surround the core completely; however the water insoluble polymer coating of the '694 patent surrounds its core. The water insoluble polymer coating of the '694 patent completely surrounds the core. The coating is thinner in the middle than on the edges and dissolves upon exposure to the aqueous environment. The thicker coating portions remain on the tablet while the thinner portions dissolve exposing the drug core. These portions are usually on the sides of the tablet, however the placement and dissolution of the coating is dependent on the thickness of the coating. It would have been obvious to combine the coating of the '694 with the core of the '200

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patent since the coating of the '200 is similar to that of the '694 with both coatings comprising ethyl cellulose. It remains the position of the Examiner that it would have been prima facie obvious to combine the coating of the '694 patent with the core of the '200 patent in order to provide sustained zero order release of active agents irrespective of the agents solubility. It has been held that "[t]he combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *Id.* at ___, 82 USPQ2d at 1395. In the instant case the multiple regions of the '200 patent are known as is the water insoluble coating of the '694 patent. This coating would provide a predictable result, namely a nearly zero order sustained release irrespective of the solubility of the active agents. The combination of these known elements would have been prima facie obvious.

Applicant argues that the combination would have been too cumbersome. Regarding this argument Applicant is reminded that "The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference.... Rather, the test is what the combined teachings of those references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 881 (CCPA 1981). See also *In re Sneed*, 710 F.2d 1544, 1550, 218 USPQ 385, 389 (Fed. Cir. 1983) ("[I]t is not necessary that the inventions of the references be physically combinable to render obvious the invention under review.") In the instant case, the '200 patent clearly suggest that the water insoluble polymer coating comprise ethyl cellulose. The coating is impermeable to an aqueous environment for a predetermined time (col. 6, lin. 15-22). This is similar to the coating of the '694 patent where the ethyl cellulose coating is impermeable to the aqueous environment for a predetermined time (col. 4, lin. 12-18). The combined teaching suggests that it would have been

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known to coat a core with a water insoluble coating in order to achieve zero order sustained release. The combination would have a single water impermeable coating, and a core with multiple regains comprising a swellable region (part 2) and an active agent region (part 1). The coating would have predetermined regions that are removed during administration (figures 2-3 '694). These disclosures render the claims obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICAH-PAUL YOUNG/

Examiner, Art Unit 1618

/Michael G. Hartley/

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